

Serial No. 10/619,932

Dkt.: P0011481.00US

Filing Date: July 15, 2003

Title: CANNULA HAVING BUCKLE RESISTANT APERTURES

### Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks and amendments presented herein, is respectfully requested. Claims 1 and 8 are amended, and claims 2, 4-5, 9, 11 and 14-22 are canceled without prejudice or disclaimer. Thus, the pending claims are claims 1, 3, 6-8, 10 and 12-13.

The amendments to the claims are fully supported by the specification as filed. No new matter has been added by way of these amendments.

The Examiner rejected claims 1, 3, 6-8, 10 and 12-13 under 35 U.S.C. §103(a) as being unpatentable over Ginsburg (U.S. Patent No. 5,180,364). In particular, the Examiner alleges that (i) FIG. 1B of Ginsburg discloses an eye-shaped aperture or “a shape having two corners having a major axis which is perpendicular to the longitudinal axis of the catheter (pages 3 and 5 of the Office Action);” and that (ii) “the apertures of Ginsburg is [*sic*] valveless” (page 4 of the Office Action). In addition, the Examiner asserts it would have been obvious to the art worker to modify the catheter of Ginsburg so as to arrive at Applicants’ claimed invention because “the plurality of rows would provide even/uniform distribution/flow” (page 4 of the Office Action). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves, or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. The teaching or suggestion to arrive at the claimed invention and the reasonable expectation of success must be found in the prior art, not in Applicant’s disclosure. M.P.E.P. § 2143 citing with favor *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As amended, the claims are directed to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system

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and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient, and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures have first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen; and to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient, and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed.

Ginsburg discloses a guiding catheter that includes an elongate body having a lumen extending therethrough, wherein the elongate body is provided with “a plurality of valved passageways” (emphasis added, column 2, lines 59-64). Ginsburg discloses that each valved passageway “acts as a one-way valve” to provide “selective communication” between the lumen and the region outside the body (column 2, lines 65-66; column 4, lines 18-25). Ginsburg further discloses that each passageway is “provided with a means for restricting fluid flow through the catheter to one direction,” such as a “valve means . . . which operates as a one-way valve” so as to “occlude the passageways so that the contents of the central lumen . . . may not pass through” (column 4, lines 26-32; column 5, lines 35-39). For example, Ginsburg discloses that when a contrast agent is injected into

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the catheter during an imaging procedure, such as angiography, the contrast agent is not “lost to the surrounding vasculature” but rather delivered by the distal end of the catheter (column 2, line 65-column 3, line 4; see also FIGs 4-7 and 10).

However, Ginsburg do not disclose or suggest to a venous cannula, let alone a valveless venous catheter comprising a body having valveless apertures. Moreover, there is nothing in Ginsburg that discloses or suggests a such a cannula having valveless apertures having first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen. Furthermore, Ginsburg does not disclose or suggest such a venous cannula having aperture corners that do not buckle outwardly as the cannula is flexed. Thus, Ginsburg does not render the pending claims obvious.

Applicants’ respectfully submit that *prima facie* obviousness has not been established. As discussed above, Ginsburg does not teach or suggest all the limitations of the pending claims. Applicants’ respectfully disagree with the Examiner’s assertion that Ginsburg discloses an aperture that is eye-shaped aperture or a shape having two corners having a major axis which is perpendicular to the longitudinal axis of the catheter. Paragraph [0027] of the application as filed discloses that an “eye-shaped aperture” is an

“aperture defined by first arcuate portion . . . and second arcuate portion . . . that intersect with one another at two tips or corners . . . [and]. . . a longer major axis . . . and a shorter minor axis . . .

Applicants’ are unable to locate the disclosure or suggestion of such an aperture in Ginsburg.

Even assuming, *arguendo*, that Ginsburg does disclose a catheter having an eye-shaped aperture or a shape having two corners having a major axis which is perpendicular to the longitudinal axis of the catheter, there is nothing in Ginsburg that discloses or suggest such a catheter having a valveless body. Ginsburg clearly discloses that his catheter has valves that block the apertures. See column 5, line 50-column 6, line 51.

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Moreover, because Ginsburg discloses that “self-perfusing guides . . . are poorly adapted for angiography techniques because large amounts of contrast media are typically lost to the surrounding vasculature,” which loss “interfere[s] with angiography” and increases the risk of contrast toxicity, Applicants’ submit that the art worker would not be motivated to remove the valves of the Ginsburg catheter, and would not have a reasonable expectation that such catheter would be successful. Furthermore, Applicants’ submit that such a modification would *render the Ginsburg catheter unsatisfactory for its intended purpose, i.e.*, removing the valves from the Ginsburg catheter would allow diffuse flow of an injected agent from the catheter, not precise delivery of the agent to a location at the distal end of the catheter. Removal of the valves from the Ginsburg catheter would cause the loss of an injected agent to the surrounding vasculature (column 2, line 66-column 3, line 1). See M.P.E.P. 2143.01(V).

Moreover, given the disclosure by Ginsburg that the passageways can be “any” shape, Applicants’ submit that Ginsburg actually *teaches away* from apertures having a particular shape, let alone apertures having “first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen” or the “eye-shaped” apertures as claimed in the present invention. Furthermore, Applicants’ submit that the disclosure by Ginsburg that the passageways can be randomly distributed on the catheter *teaches away* from apertures having a particular pattern of distribution, let alone apertures that are “arranged into a plurality of rows generally extending along the longitudinal axis of the lumen” and apertures that are “evenly distributed on the body . . . offset such that the apertures in the adjacent rows are different distances from a distal tip of the body” as claimed in the present invention.

Therefore, for the reasons discussed above, it is respectfully submitted that the pending claims are not *prima facie* obvious over Ginsburg. Withdrawal of the 35 U.S.C. §103(a) rejection of the claims is thus proper and respectfully requested.

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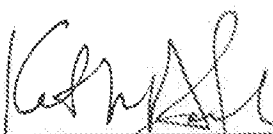
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**Conclusion**

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to telephone Applicants' Representative at 763-505-8423 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

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By   
Katharine A. Jackson Huebsch  
Reg. No. 47,670  
MEDTRONIC, INC.  
MS LC 340  
710 Medtronic Parkway  
Minneapolis, MN 55432  
Tel. 763-505-8423  
Fax. 763-505-8436  
Customer No. 27581